IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

Q-MED AB, Plaintiff, v. OCEANA THERAPEUTICS, INC. (f/k/a Q-MED SCANDINAVIA INC.), OCEANA THERAPEUTICS LTD. (f/k/a CETACEA LIMITED), SALIX PHARMACEUTICALS, INC., VALEANT PHARMACEUTICALS INTERNATIONAL, INC., and VALEANT PHARMACEUTICALS IRELAND, Defendants.	Case No. _____ **COMPLAINT**

Plaintiff Q-Med AB ("Q-Med" or "Plaintiff"), by its undersigned attorneys, as and for its Complaint against defendants, alleges as follows:

NATURE OF THIS ACTION

1. This is an action for a declaratory judgment pursuant to 28 U.S.C. § 2201 and Federal Rule of Civil Procedure 57 to determine and resolve an actual controversy regarding Q-Med's right to terminate license agreements entered into with Defendant Oceana Therapeutics, Inc., f/k/a Q-Med Scandinavia Inc. ("Oceana").

2. Specifically, this action seeks a declaratory judgment that Oceana, along with Defendants Salix Pharmaceuticals ("Salix"), Valeant Pharmaceuticals International, Inc. ("Valeant"), and Valeant Pharmaceuticals Ireland ("Valeant Ireland," and collectively with

Oceana, Salix, and Valeant, "Defendants") have, since 2014, repeatedly defaulted under the license agreement covering the United States territory (the "U.S. License Agreement"), which was entered into with Q-Med on June 2, 2009.

3. As explained more fully below, in default of the U.S. License Agreement, Defendants have failed to adequately market, provide training, and otherwise support two medical device products manufactured by Q-Med, namely Solesta® and Deflux® (the "Licensed Products"), since at least 2014, and possibly earlier.

4. Solesta® and Deflux® are, generally, speaking, bulking agents. Solesta® is used to treat fecal incontinence ("FI") in adults and Deflux® is used to treat vesicoureteral reflux ("VUR") in children. Both devices are minimally invasive treatments that may obviate the need for surgery or antibiotic treatments.

5. Defendants' defaults of the U.S. License Agreement have resulted in, among other things, inadequate education and marketing to the U.S. medical community and patients, regarding the use of Solesta® and Deflux®. As explained more fully below, both Solesta® and Deflux® require administration by qualified surgeons, who have necessary training with the particular product, making physician outreach and training essential to the products' use and success. Such lack of physician training regarding proper use of the Licensed Products not only threatens to render Solesta® and Deflux® obsolete within the U.S. medical community, but also risks undermining their regulatory approval by running afoul of federal statutes and regulations.

6. Despite Defendants' defaults, Defendants have refused to consent to terminate the U.S. License Agreement, necessitating a declaratory judgment that Defendants

have defaulted under the U.S. License Agreement, and that Plaintiff may accordingly lawfully terminate the U.S. License Agreement and other associated agreements based upon cross-termination provisions contained in those agreements.

7. Upon termination, the premarket approval application ("PMA"), which is the document which triggers FDA review and defines the scope of FDA approval, would be transferred from Oceana to Q-Med.

THE PARTIES

8. Plaintiff Q-Med is a corporation organized under the laws of the Kingdom of Sweden, with its principal place of business located at Fyrisvallsgatan 7, 752 28 Uppsala, Sweden.

9. Defendant Oceana is a corporation organized under the laws of the State of Delaware, with its principal place of business located at 2035 Lincoln Highway, Edison, New Jersey 08817.

10. Defendant Oceana Therapeutics Ltd. (formerly known as Cetacea Limited) ("Oceana Limited") is a corporation organized under the laws of Ireland, with its principal place of business located at 602, 76 Furze Rd., Dublin, Ireland.

11. Defendant Salix is a corporation organized under the laws of California, with its principal place of business located at 8510 Colonnade Center Drive, Raleigh, NC 27615.

12. Defendant Valeant is a corporation organized under the laws of Canada, with its principal place of business located at 2150 St. Elzéar Blvd. West, Laval, Quebec H7 4A8, Canada.

13. Defendant Valeant Ireland is an unlimited liability company organized under the laws of Ireland, with its principal place of business located at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

14. Upon information and belief, Salix acquired Oceana on or around December 20, 2011, and Valeant acquired Salix on or around April 1, 2015.

JURISDICTION AND VENUE

15. Jurisdiction is proper in this Court pursuant to diversity of citizenship. See 28 U.S.C. § 1332. Complete diversity of citizenship exists because this action involves a dispute among citizens of different states and the amount in controversy exceeds $75,000, exclusive of interest and costs.

16. This Court has personal jurisdiction over Defendants because they contractually consented to jurisdiction in the United States District Court for the Southern District of New York ("S.D.N.Y.") under the U.S. License Agreement.

17. Venue is also properly based in the S.D.N.Y. pursuant to the U.S. License Agreement, which states:

> **Consent to Jurisdiction.** EACH PARTY HERETO IRREVOCABLY AND UNCONDITIONALLY (A) SUBMITS FOR ITSELF AND ITS PROPERTY, TO THE **EXCLUSIVE JURISDICTION** OF THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK WITH RESPECT TO ANY CLAIM SEEKING DECLARATORY OR EQUITABLE RELIEF ARISING UNDER OR RELATING TO THIS AGREEMENT [...]

(See U.S. License Agreement § 12.3) (emphasis added).

18. A declaratory judgment that Defendants defaulted under the U.S. License Agreement is appropriate pursuant to 28 U.S.C. § 2201 because declaratory relief will resolve a definite and concrete controversy between the parties.

FACTUAL ALLEGATIONS

The License Agreements

19. Solesta® is an injectable gel used to treat FI, for use by patients 18 years or older.

20. Deflux® is an injectable gel liquid used to treat VUR, which is an abnormal condition in which urine flows backwards from the bladder into the kidneys, causing repeated and severe urinary tract infections. Deflux® is used primarily to treat pediatric patients, and is the only treatment of VUR of its kind that is approved for use in the United States. Other treatments for VUR include long-term antibiotic use or invasive surgery.

21. Solesta® and Deflux® are administered using a specialized needle, which, as explained below, is a device that is also the subject of a license agreement between the parties. Both products require a high degree of specialized training for their use. Accordingly, the Deflux® Instructions for Use ("IFU") state that it is "to be administered only by qualified surgeons experienced in the use of a cystoscope and trained in the technique of subureteric and/or intraureteric injections." Similarly, the Solesta® IFU states that it is "only to be administered by physicians experienced in performing anorectal procedures and who have successfully completed a comprehensive training and certification program in the Solesta injection procedure."

22. Indeed, use of Solesta® and Deflux® requires in-depth, in-person training. The procedure for administering these devices requires extremely exact precision, allowing no more than a few millimeters of diversion. This precision is critical for the pediatric patients using Deflux®.

23. In an effort to obtain an exclusive collaborator to provide such advanced training and help market Solesta® and Deflux®, Q-Med entered into the U.S. Licensing Agreement with Q-Med Scandinavia Inc. (now known as Oceana) on or about June 2, 2009. The intent of the U.S. Licensing Agreement was for Q-Med and Oceana to work together, through a joint steering committee, to educate the U.S. medical community, as well as patients and parents of pediatric patients, about the treatment benefits of Deflux® and Solesta®, and, in so doing, increasing awareness and use of these products.

24. On the same day as the execution of the U.S. License Agreement, June 2, 2009, Oceana acquired all of the outstanding capital stock of Q-Med Scandinavia Inc., pursuant to a Stock Purchase Agreement dated as of April 22, 2009 (the "SPA").

25. On or around June 2, 2009, Q-Med and Cetacea Limited (now known as Oceana Limited) concurrently executed another License Agreement, covering the Rest of the World ("ROW"), or the territory defined as worldwide excluding the United States (the "ROW License Agreement").

26. On or around June 2, 2009, Q-Med and Oceana concurrently executed a U.S. Supply Agreement (the "U.S. Supply Agreement") and Quality Agreement (the "U.S. Quality Agreement," and collectively with the Supply Agreement and the U.S. License Agreement, the "U.S. Oceana Agreements").

27. On or around June 2, 2009, Q-Med and Oceana Limited concurrently executed a ROW Supply Agreement (the "ROW Supply Agreement") and Quality Agreement (the "ROW Quality Agreement," and collectively with the Supply Agreement and the ROW License Agreement, the "ROW Oceana Agreements").

28. The U.S. Oceana Agreements and ROW Oceana Agreements all contain cross-termination provisions, under which termination of the U.S. License Agreement gives Q-Med the right to terminate all of the U.S. and ROW Oceana Agreements. (See U.S. and ROW Supply Agreements at § 6.2(c); U.S. and ROW Quality Agreements § 6.1; U.S. and ROW License Agreement § 11.5; U.S. License Agreement § 11.5.)

29. Pursuant to the U.S. Supply Agreement, Q-Med is required to manufacture and supply all of Defendants' requirements for the Licensed Products. (See U.S. Supply Agreement § 2.1.)

30. Under the U.S. License Agreement, Defendants are required to use "Commercially Reasonable Efforts" to "optimize Commercialization of the Licensed Products" within the U.S. and ROW. (See U.S. License Agreement § 5.1(a).)

31. The U.S. License Agreement defines "Commercially Reasonable Efforts" as follows:

> "Commercially Reasonable Efforts" means, with respect to [Oceana], exerting such effort and employing such resources as would normally be exerted or employed by a U.S. specialty pharmaceutical company of comparable revenues, assets, and committed capital resources as [Oceana] […]

(See U.S. License Agreement § 1.1.)

32. The U.S. License Agreement defines "Commercialization" and "Commercialize" as follows:

> "Commercialization or Commercialize" means any and all activities directed to (i) marketing, promoting, distributing, importing, offering to sell and/or selling the Licensed Products, including market research, seeking appropriate reimbursement, billing and coding support for physicians and clinics, product related public relations, planning, detailing marketing, distribution, creative development of visual sales aids, direct mail, telemarketing and teladetailing, media placement and advertising, field marketing events, and sales meetings; and

> (ii) medical affairs support (including medical education programs, medical meetings and educational grants, regulatory affairs and quality assurance support (including adverse event reporting and post-market surveillance studies, whether for marketing purposes, post-marketing experience investigations, regulatory compliance or as a condition to obtaining, maintaining, or amending Regulatory Approval). [...]

(See U.S. License Agreement § 1.1.)

33. The U.S. License Agreement enumerates specific Commercialization activities Defendants are required to conduct in the United States, including, but not limited to:

a) Provide a U.S. sales organization to promote the Licensed Products, including sales, sales training and marketing management personnel and product related injection training for users, such as physicians;

b) Sponsor and provide medical education, advocate development and training related to the Licensed Product in the United States, including support from scientific affairs liaisons;

c) Seek appropriate reimbursement coding in the United States, including separate product codes issued by, for example, the U.S. Centers for Medicare and Medicaid Services;

(See U.S. License Agreement § 5.1(b)-(d).)

34. In exchange for the foregoing promises, Q-Med granted Oceana the exclusive license to Commercialize the Licensed Products in the United States for the term of the U.S. License Agreement. (See U.S. License Agreement § 2.4.)

35. Defendants are also required to pay royalties to Q-Med based on its sales of the Licensed Products. (See U.S. License Agreement § 1.1.)

36. The U.S. License Agreement allows for termination in the event of a default by either party, stating, in part:

> **Termination for Default.** If either party (**"Breaching Party"**) commits a material breach of a material obligation under this Agreement, the other Party (**"Terminating Party"**) may terminate this Agreement.

(See U.S. License Agreement § 11.3.)

37. The U.S. License Agreement provides that Q-Med is entitled to attorney's fees from Defendants in the event that Q-Med prevails in any action in which Q-Med obtains a judgment from Defendants. (See License Agreement § 12.11.)

38. Three years after the execution of the U.S. and ROW Oceana Agreements, Q-Med entered into an additional license agreement with Oceana and Oceana Limited, under which Q-Med agreed to grant Oceana and Oceana Limited a license to, among other things, obtain worldwide regulatory approvals of a specific needle to be used for injections of the Deflux® Licensed Product (the "Needle Agreement").

39. Like the U.S. and ROW Oceana Agreements, the Needle Agreement contains a cross-termination provision, whereby termination of the U.S. License Agreement gives Q-Med the right to terminate the Needle Agreement. (See Needle Agreement § 5.1.)

40. On or around December 20, 2011, Defendant Salix completed the acquisition of all of the outstanding stock of Defendant Oceana Therapeutics, Inc.

41. On or around April 1, 2015 Defendant Valeant purchased all of the shares of Defendant Salix's common stock.

42. Valeant and Oceana purportedly assigned the U.S. and ROW License Agreements, as well as the Needle Agreement to Valeant Ireland, by sublicense agreement dated as of December 31, 2015 (the "Sublicense Agreement"). Q-Med was not made aware of the Sublicense Agreement until approximately April of 2016.

Q-Med's Performance

43. Since the execution of the License Agreement on June 2, 2009, Q-Med has performed all of its obligations under the agreements, including, but not limited to, granting Oceana the exclusive license to Commercialize the Licensed Products in the United States.

44. Furthermore, Q-Med has performed all of its obligations under the U.S. and ROW Supply Agreements and Quality Agreements, including, but not limited to, manufacturing and supplying all of Oceana's requirements for the Licensed Product.

Defendants' Multiple Defaults Since at Least 2014

45. Upon information and belief, Defendants have been defaulting on their obligation to use Commercially Reasonable Efforts to Commercialize the Licensed Products since at least 2014, and possibly earlier. These ongoing defaults include, but are not limited to:

a) Directing its sales force to de-emphasize Deflux® in early 2015, in violation of Section 5.1(b)(i) of the U.S. License Agreement;

b) Failing to adequately market Deflux®, in violation of Sections 5.1(b)(i)-(ii) and 5.1(d) of the U.S. License Agreement;

c) Excluding Deflux® as a commissioned product for its sales force as of July 2015, and instructing its sales force to not promote Deflux® and Solesta®, in violation of Sections 5.1(b)(i)-(ii) and 5.1(d) of the U.S. License Agreement;

d) Failing to send a sales representative for Deflux® to opinion leaders and leading users of Deflux® in the U.S. for at least a year, in violation of Sections 5.1(b)(i)-(ii) and 5.1(d) of the U.S. License Agreement;

e) Failing to provide customary customer support after July 1, 2015;

f) Failing to provide training support of hospital staff, new medical residents, current users and new users resulting in no training for incoming pediatric urologists with respect to the Licensed Products, in violation of Section 5.1(b)(iii) of the U.S. License Agreement;

g) Failing to represent Deflux® at medical meetings and conferences in the United States;

h) Failing to provide marketing plans for 2016 that adequately describe how Defendants intend to promote the Licensed Products, or the sales, marketing, and advertising campaigns to be conducted in 2016, in violation of Section 5.1(b) of the U.S. License Agreement;

i) Failing to enact sufficient procedures to enable Defendants to perform its obligations to coordinate the collection, investigation, reporting and exchange of information concerning adverse events with respect to the Licensed Products, in violation of Section 4.4 of the U.S. License Agreement;

j) Failing to comply with the detailed sublicense requirements outlined in the U.S. License Agreement;

k) Postponing all purchases of the Solesta® Licensed Product in 2016, in anticipation of a sharp decline in expected Solesta® sales; and

l) Failing to instruct Valeant's representatives to promote Deflux® at the American Urological Association's 2016 meeting in San Diego, California.

46. Upon information and belief, the foregoing failures by Defendants constitute defaults of Defendants' obligations under the U.S. License Agreement, as Defendants have failed to use Commercially Reasonable Efforts to Commercialize the Licensed Products.

47. Upon information of belief, these defaults, occurring since at least 2014, have resulted in decreased sales of the Licensed Products in the United States.

48. Furthermore, upon information and belief, Defendants' defaults have resulted in damage to the Licensed Product's reputation in the United States, as Defendants have failed to adequately market the Licensed Products or educate the medical community about the Licensed Products.

49. Additionally, these defaults have resulted in a lack of training within the medical community and in hospitals on how to administer and use Solesta® and Deflux®, both

of which involve highly complicated procedures with very little room for error. Such lack of training, if allowed to continue, could render the Licensed Products obsolete within a few years.

50. In addition to constituting a default under the U.S. License Agreement, Defendants' failure to adequately train physicians to properly utilize Solesta® and Deflux® may run afoul of federal law and FDA regulations, which require that a device be marketed only in a manner that comports with the FDA's premarket approval conditions. *See generally* 21 U.S.C. §§ 501-02; 21 C.F.R. § 801. As explained above, both the IFU's for Solesta® and Deflux®, which have been subject to FDA review and approval, require that users of both products are extensively trained physicians and surgeons. *See* ¶ 21, *supra*. These defaults by Defendants carry the risk of jeopardizing the Licensed Products' FDA approval.

51. As a result of the foregoing defaults, Plaintiff is entitled to terminate the U.S. License Agreement pursuant to Section 11.3 of the U.S. License Agreement.

52. Moreover, pursuant to the cross-termination provisions contained the Supply Agreements, Quality Agreements, and ROW License Agreement, Plaintiff is entitled to terminate those agreements as well based upon Defendants' defaults under the U.S. License Agreement.

53. Upon information and belief, on December 31, 2015, Oceana and Oceana Limited entered into a sublicense agreement with an affiliate of Valeant, under which Oceana and Oceana Limited purportedly sublicensed their rights under the U.S. and ROW License Agreements.

54. On May 24, 2016, Q-Med notified Defendants of Defendants' ongoing defaults, pursuant to Section 11.3 of the U.S. License Agreement. Because these defaults are not

capable of being cured by Defendants, as they have been continuing since at least 2014, and possibly earlier, Q-Med elected to terminate the U.S. Oceana Agreements, the ROW Oceana Agreements and the Needle Agreement.

55. Following Q-Med's May 24, 2016 notice of default, Defendant Valeant verbally communicated to Q-Med that it did not believe that it was in default under the U.S. License Agreement, and would not consent to termination.

FIRST CAUSE OF ACTION
DECLARATORY JUDGMENT
(AGAINST ALL DEFENDANTS)

56. Plaintiff repeats and realleges each of the foregoing allegations, as if fully stated herein.

57. A substantial and actual controversy exists as to whether Defendants have defaulted under the U.S. License Agreement, and if Plaintiff is accordingly entitled to terminate the U.S. License Agreement and other U.S. and ROW Oceana Agreements by and between Plaintiff and Defendants.

58. By reason of the foregoing, Plaintiff seeks a declaration, pursuant to 28 U.S.C. § 2201, that Defendants defaulted under the U.S. License Agreement and that Plaintiff is entitled to terminate the U.S. License Agreement and U.S. and ROW Oceana Agreements by and between Plaintiff and Defendants.

59. Q-Med reserves the right to assert defaults of the other U.S. and ROW Oceana Agreements in this action or any other action.

WHEREFORE, Plaintiff requests judgment against Defendants as follows:

a) Declaring the U.S. License Agreement terminated based on Defendants' defaults; and

b) Declaring that Q-Med has the right to terminate all of the U.S. and ROW Oceana Agreements, as well as the Needle Agreement, based upon Defendants' defaults and the cross-termination provisions in the Agreements;

c) Awarding Q-Med attorney's fees and costs related to bringing this action, as required by Section 12.11 of the U.S. License Agreement; and

d) Granting such other relief as this Court may deem just and proper, including but not limited to equitable and injunctive relief.

Dated: New York, New York
July 14, 2016

MORRISON COHEN LLP

By: /s/ Danielle C. Lesser

Danielle C. Lesser
Edward P. Gilbert
Andrew P. Merten
909 Third Avenue
New York, New York 10022
Tel: (212) 735-8600
Fax: (212) 735-8708
dlesser@morrisoncohen.com
egilbert@morrisoncohen.com
amerten@morrisoncohen.com

Attorneys for Plaintiff